

This listing of claims will replace all prior versions and listings of claims in the application:

LISTING OF CLAIMS:

1-27. (canceled)

28. (original) A method for evaluating the stability of drug samples when exposed to various controlled conditions, the method comprising:

 providing an array of drug samples;

 simultaneously exposing a plurality of the drug samples to at least one controlled environmental condition for an exposure period;

 simultaneously exposing the plurality of the drug samples to at least one controlled chemical condition for the exposure period; and

 evaluating any change of the exposed drug samples.

29. (original) The method of claim 28, wherein the plurality of drug samples exposed to the controlled environmental condition and the plurality of drug compositions exposed to the chemical condition are drug candidates.

30. (original) The method of claim 28, wherein the plurality of drug samples are exposed in a chamber.

31. (canceled)

32. (original) The method of claim 28, wherein at least two of the drug samples of the array are different from each other.

33. (original) The method of claim 28, wherein at least one of the drug samples is exposed to a first controlled chemical condition and at least one other drug

sample is exposed to a second controlled chemical condition different from the first controlled chemical condition.

34. (original) The method of claim 28, wherein at least one of the drug samples is exposed to a first controlled environmental condition and at least one other drug sample is exposed to a second controlled environmental condition different from the first controlled environmental condition.

35. (original) The method of claim 28, wherein the drug samples are drug compositions.

36. (original) The method of claim 28, wherein at least one of the drug samples is a drug candidate and at least one of the drug samples is a drug composition.

37. (original) The method of claim 28, wherein the change in the exposed drug samples is a change in chemical composition of an active pharmaceutical ingredient.

38. (original) The method of claim 28, wherein the change in the exposed drug samples is a change in biological activity of the drug candidate.

39. (original) The method of claim 28, wherein the change in the exposed drug samples is a change in component compatibility.

40. (original) The method of claim 28, wherein a plurality of the drug samples of the array comprise a chemical selected from the group consisting of acids, bases, radicals and oxidizers.

41. (original) The method of claim 28, wherein the controlled environmental condition is selected from the group consisting of heat, humidity and light.

42. (original) The method of claim 28, wherein the drug samples of the array all have

chemical or physical diversity.

43. (original) The method of claim 28, wherein the drug compositions of the array are the same.

44. (original) The method of claim 42, wherein at least one of the drug samples of the plurality of drug samples exposed to at least one controlled chemical condition is exposed to a first controlled chemical condition and at least one other drug sample of the plurality of drug samples exposed to at least one controlled chemical condition is exposed to a second controlled chemical condition different from the first controlled chemical condition.

45. (original) The method of claim 43, wherein at least one of the drug samples of the plurality of drug samples exposed to at least one environmental condition is exposed to a first controlled environmental condition and at least one other drug sample of the plurality of drug samples exposed to at least one controlled environmental condition is exposed to a second controlled environmental condition different from the first controlled environmental condition.

46. (original) The method of claim 42, wherein at least one of the drug samples of the plurality of drug samples exposed to at least one controlled environmental condition is exposed to a first controlled environmental condition and at least one other drug sample of the plurality of drug samples exposed to at least one controlled environmental condition is exposed to a second controlled environmental condition different from the first controlled environmental condition.

47. (original) The method of claim 45, wherein at least one of the drug samples of the

plurality of drug samples exposed to at least one controlled chemical condition is exposed to a first controlled chemical condition and at least one other drug sample of the plurality of drug samples exposed to at least one controlled chemical condition is exposed to a second controlled chemical condition different from the first controlled chemical condition.

48.(original) The method of claim 28, further comprising testing the exposed drug samples at least twice, wherein at least one of said tests is performed during the exposure period.

49.(original) The method of claim 48, wherein the testing is non-destructive.

50.(original) The method of claim 49, wherein the non-destructive test is selected from the group consisting of raman spectroscopy, X-ray diffraction, near infrared spectroscopy, dynamic light scattering and ultraviolet-visible spectroscopy.

51.(original) The method of claim 48, further comprising conducting a destructive test after the exposure period.

52.(original) The method of claim 48, wherein the testing is destructive.

53.(original) The method of claim 28, further comprising preparing the array of drug samples.

54.(original) The method of claim 28, further comprising daughtering the array into at least four additional arrays before exposure, resulting in at least a first array, a second array, a third array, a fourth array and a fifth array.

55.(original) The method of claim 54, wherein a plurality of the drug samples of the first array is exposed to a first controlled temperature condition, a plurality of the drug samples of the second array is exposed to a second controlled temperature

condition different from the first temperature condition, a plurality of the drug samples of the third array is exposed to a first controlled humidity condition, a plurality of the drug samples of the fourth array is exposed to a second controlled humidity condition different from the first humidity condition and a plurality of the drug samples of the fifth array is exposed to a controlled light condition.

56. (original) The method of claim 28, wherein the array is located on a common substrate.

57. (original) The method of claim 56, wherein each drug sample of the array is located on a spatially discrete region of the substrate.

58. (original) The method of claim 28, wherein the drug compositions of the array contain no more than 10 mg of active pharmaceutical ingredient.

59. (original) The method of claim 28, wherein a plurality of the drug samples of the array comprise an excipient selected from the group consisting of lubricants, surfactants, diluents, binders, fillers and disintegrants.

60. (original) The method of claim 28, wherein a plurality of the drug samples of the array comprise a chemical selected from the group consisting of acids, bases, radicals and oxidizers.

61. (currently amended) The method of claim 28, further comprising placing the array of drug samples in [[a]] an exposure test chamber.

62-134. (canceled)

135. (new) A method for evaluating the stability of drug samples when exposed to various controlled conditions, the method comprising:
providing an array of drug samples;

simultaneously exposing a plurality of the drug samples to at least one controlled environmental condition for an exposure period;

simultaneously exposing the plurality of the drug samples to at least one controlled chemical condition for the exposure period; and

evaluating any change of the exposed drug samples;

wherein at least one of the drug samples is exposed to a first controlled chemical condition and at least one other drug sample is exposed to a second controlled chemical condition of a type different from the first controlled chemical condition; and, further wherein at least one of the drug samples is exposed to a first controlled environmental condition and at least one other drug sample is exposed to a second controlled environmental condition of a type different from the first controlled environmental condition.

136. (new) The method of claim 135, wherein the plurality of drug samples are exposed in a chamber.

137. (new) The method of claim 135, wherein at least two of the drug samples of the array are different from each other.

138. (new) The method of claim 135, wherein the drug samples are drug compositions.

139. (new) The method of claim 135, wherein the change in the exposed drug samples is a change in chemical composition of an active pharmaceutical ingredient.

140. (new) The method of claim 135, wherein the change in the exposed drug

samples is a change in biological activity of the drug candidate.

141. (new) The method of claim 135, wherein the change in the exposed drug samples is a change in component compatibility.

142. (new) The method of claim 135, wherein a plurality of the drug samples of the array comprise a chemical selected from the group consisting of acids, bases, radicals and oxidizers.

143. (new) The method of claim 135, wherein the first controlled environmental condition is selected from the group consisting of heat, humidity and light, and further wherein the second controlled environmental condition is different from the first controlled environmental condition and is selected from the group consisting of heat, humidity and light.

144. (new) The method of claim 135, wherein the drug samples of the array all have chemical or physical diversity.

145. (new) The method of claim 135, wherein the drug compositions of the array are the same.

146. (new) The method of claim 135, further comprising testing the exposed drug samples at least twice, wherein at least one of said tests is performed during the exposure period.

147. (new) The method of claim 146, wherein the testing is non-destructive.

148. (new) The method of claim 147, wherein the non-destructive test is selected from the group consisting of raman spectroscopy, X-ray diffraction, near infrared spectroscopy, dynamic light scattering and ultraviolet-visible spectroscopy.

149. (new) The method of claim 147, wherein the non-destructive test is an optical

test.

150. (new) The method of claim 146, further comprising conducting a destructive test after the exposure period.

151. (new) The method of claim 146, wherein the testing is destructive.

152. (new) The method of claim 135, wherein the array is located on a common substrate.

153. (new) The method of claim 152, wherein each drug sample of the array is located on a spatially discrete region of the substrate.

154. (new) The method of claim 135, wherein the drug compositions of the array contain no more than 10 mg of active pharmaceutical ingredient.

155. (new) The method of claim 49, wherein the non-destructive test is an optical test.